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10/585,693	11/09/2006	Takashi Yamashita	Q95455	4348

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
10/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,693	YAMASHITA ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23 and 25-30* is/are pending in the application.

4a) Of the above claim(s) *7-23 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/19/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status

Applicants' response of June 19, 2008, to the non-final action dated March 19, 2008, has been entered. Claims 1-23 and 25-30 are pending in the application. Claim 1 has been amended and claim 24 cancelled. No claims were newly added. Claim 7-23 and 28-30 stand withdrawn from further consideration, without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claims 1-6 and 25-27 are under current examination. The claims have been examined commensurate in scope with the elected species of chicken.

Response to Information Disclosure Statement

The previous office action dated March 19, 2008 indicated that JP 2001-520009 was submitted in the Japanese language, and that only the English language Abstract for JP 2002-176880 was considered in the information disclosure statements filed 7/10/2006 and 11/9/2006. Applicants have indicated that the each of the Information Disclosure statements set forth the degree of relevance of the references, as cited in a communication from a Foreign Patent Office, except for JP 2001-520009, thus an English translation is not required. With regard to JP 2001-520009, Applicants have provided WO 99/19472 as containing the same disclosure.

Accordingly, the JP documents have been indicated as considered on form PTO/SB08a, submitted 6/19/2008.

Response to Objection to Drawings

The drawings were objected to in the previous office action dated March 19, 2008, as incorrectly numbered. Applicants have provided new drawings corresponding to Figures 3a and 3b, thus obviating the ground for objection. Accordingly, the previous objection is hereby withdrawn.

Response to Claim Rejections - 35 USC § 102

Claims 1-6 and 24 were rejected under 35 U.S.C. 102(e) as being anticipated by Sang et al. (U.S. Patent Application Publication 2005/0273872), as evidenced by Kamachi et al. (Development 125:2521-2532; 1998), in the previous office action dated March 19, 2008. Applicants' cancellation of claim 24 renders its rejection moot. Applicants have amended base claim 1 to introduce the new limitation: "wherein the replication-deficient retroviral vector is derived from Moloney murine leukemia virus", not taught by Sang et al. Accordingly, the rejection of claims 1-6 is hereby withdrawn. Applicants' arguments are moot in view of the withdrawn rejection. The claims are however, subject to a new rejection over the prior art, as indicated below.

Claims 25-27 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ransohoff et al. (U.S. Patent Application Publication 2003/0176660; effective filing date Feb. 8, 2002). The rejection set forth on page 5 of the previous office action dated March 19, 2008 is maintained for reasons of record.

Applicants disagree with the rejection, arguing that the claimed product is distinguishable over that of Ransohoff et al. due to the integration of the Moloney murine leukemia-specific sequences in the delivery of the vector and which are stably integrated into the avian genome, and thus necessarily present within Applicants' egg as claimed. Applicants' arguments have been fully considered, but are not deemed persuasive.

As an initial matter, it should be noted that the process steps recited in claim 1 result in transgenic chimeric chickens, especially when mating G0 chimerics to another unrelated G0 chimeric chicken, or a wild-type bird. Thus, germline transmission of the transgene is not

necessarily achieved, and hence the transgene need not be present in the egg. Thus, Applicants' assertions are incorrect. Moreover, the instant claims are directed to an egg laid by a chicken, containing varying amounts of a desired protein, therefore the features upon which applicant relies (i.e., Moloney murine leukemia-specific sequences) are not recited in the rejected claim(s).

As previously indicated, the structural elements of the transgenic chicken egg, specifically that it possesses various amounts of a desired protein are given patentable weight. The source of the eggs, i.e. the transgenic hen producing the egg, or the method of producing said transgenic hen are not afforded patentable weight, as it is assumed that equivalent transgenic egg products may be obtainable from transgenic hens produced by different methods.

Applicants further argue that Ransohoff et al. is not valid anticipatory prior art because it lacks an enabling disclosure to produce an egg containing the claimed amount of transgene-encoded protein, and provides no guidance to the skilled artisan as to how to produce an egg encompassed by the instant claims.

Such is not found persuasive, because, the Federal Circuit has made it clear that the level of enablement necessary for a reference applied under 102 is not identical to the enablement requirement applied to an application that is under examination. See for example the opinion issued November 20, 2006 in *IMPAX LABORATORIES, INC., v. AVENTIS PHARMACEUTICALS INC.*, CAFC docket number 05-1313. When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP §716.07." In the instant case, Applicant has provided no evidence that that the cited prior art is inoperable. Moreover, there is no requirement for Ransohoff et al. to teach the production of transgenic or chimeric chicken, when such was known in the prior art. In a 35 U.S.C. 102(e)/103(a) rejection over a prior art patent, the reference patent is available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed. *In re Bowers*, 359 F.2d 886, 149 USPQ 570 (CCPA 1966).

Thus, the rejection of claims 25-27 is maintained for reasons of record and the foregoing discussion.

New Claim Rejections - 35 USC § 103

Applicants' claim amendments have necessitated the following new grounds of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sang et al. (U.S. Patent Application Publication 2005/0273872), as evidenced by Kamachi et al. (Development 125:2521-2532; 1998), in view of Rapp, J. (U.S. Patent Publication No. 2002/0108132, effective filing date Feb. 2, 2001).

The claims embrace G1 and G2 transgenic chickens or an offspring thereof, comprising a replication-deficient retroviral vector derived from Moloney murine leukemia virus, coding for a desired protein, or an antibody.

With respect to claims directed to the G1 (and G2) transgenic chicken, they are determined to be a product-by-process claims. The structural elements of the transgenic chicken, specifically that it possesses a replication defective retroviral vector encoding a desired protein are given patentable weight. The recitation of a process limitation in claim 1 is not viewed as positively limiting the claimed product absent a showing that the process of making imparts a novel or unexpected property to the claimed transgenic chicken product, as it is assumed that equivalent transgenic chicken products are obtainable by multiple routes. The recitation "obtainable by" is not considered to limit the claimed transgenic chicken because the G1 and G2 transgenic chickens may be obtained by other reproductive means. The burden is placed upon the applicants to establish a patentable distinction between the claimed and referenced products. The method in which the transgenic chickens were produced is immaterial to their patentability.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP §2113.

Sang et al. describe the generation of transgenic avians and the expression of transgene encoded protein within the avian egg (Title and Abstract). Replication defective vectors, such as ALV and other lentiviruses are described in paragraph [0013], on p. 2 and paragraph [0017], p. 3. Lentiviruses are described as a subgroup of the retroviruses (paragraph [0015], p. 3). Sang et al. specifically disclose obtaining fertile hen's eggs containing developing chick embryos at developmental stages X-XIII ; and injection of VSV-G peudotyped lentiviral vector into the subgerminal cavity below the embryo (Experiment 1, paragraph [0064], p. 5), to produce G0 transgenic chickens (paragraph [0090], p. 7).

Stage 13 chick embryos include the gastrula stage, i.e. up to and including 48 hours; such is evidenced by Kamachi et al. in describing the expression of the lens-specific crystallin gene in the developing chicken (first column, under summary; limitation of claims 2 and 3).

Germ line transmission from G0 males and breeding by crossing to stock hens and screening their G1 offspring is described in paragraph [0092], p. 7. The analysis of G1 transgenic birds and transmission to G2 from the founder birds is described in paragraphs [0093-0095], p. 7 (limitation of claim 6). Transgene expression in G1 and G2 transgenic birds is disclosed in paragraph [0096], pp. 7-8. Sang et al. further state that the transgene material may encode any of a large number of proteins, and may include sequences encoding antibodies (paragraph [0030], p. 4; limitation of claim 4).

While Sang et al. do not describe the production of transgenic chimeric chicken using a retroviral vector derived from Moloney murine leukemia virus, such was known in the prior art.

Rapp et al. describe transgenic chickens (Abstract and p. 4, paragraph [0041]), transformed with recombinant retroviral expression vectors, including a Moloney murine leukemia virus-derived vector (p. 5, paragraphs [0052 and 0054]; p. 9, paragraphs [0094-0095];

pg 16, [0158]), wherein said vectors comprise a gene encoding [chimeric] antibodies comprising human immunoglobulin constant domains, single-chain antibodies, and antibody fragments and/or from birds or mice (pp. 6-7, paragraphs [0062-0068]; p. 15, paragraph [0151]; p. 16, paragraph [0161]) operably linked to, for example, to a chicken oviduct-specific promoter such as ovalbumin (p. 9, paragraph [0090]; p. 16, paragraph [0159]) and Example 5, p. 19.

The teachings of Sang et al., and Rapp et al. are all directed to the production of transgenic chickens using retroviral-derived vectors. Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine their respective teachings to utilize the Moloney murine leukemia virus-derived vector of Rapp et al., in the method of Sang et al. as instantly claimed, as a matter of design choice, with a reasonable expectation of success, at the time of the instant invention. Said design choice amounting to combining prior art elements according to known methods to yield predictable results. Applicants should note that the *KSR* case forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. *KSR International Co. v. Teleflex Inc.*, 550 U.S.-, 82USPQ2d 1385 (2007).

Response to Arguments Relating to the Sang et al. Reference

Applicants state that base claim 1 has been amended to recite that the replication-deficient retroviral vector "is derived from Moloney murine leukemia virus."; and Sang et al. is in paragraph [0016], state that the use of a delivery vector derived from Moloney murine leukemia virus during development leads to gene silencing, and "very low expression of the transgene" . In response, it should be noted that the foregoing has been quoted out of context. While Sang et al. state that it is essential that any viral vector used for production of transgenic birds does not exhibit gene silencing, the reference to Moloney murine leukemia virus is from the teachings of Jahner et al. published in 1982, directed to de novo methylation and expression of retroviral genomes during mouse embryogenesis (paragraphs [0016 and 0129]. Therefore, the teachings of Jahner et al. are not necessarily extendable to chickens, especially given the body of subsequent publications with regard to using Moloney murine leukemia virus as an expression vector in chimeric or transgenic birds.

Response to Obviousness Type Double Patenting

Claims 1-6 and 24 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-10 and 22 of copending U.S. Patent Application No.: 10/569,268 (2006/0259997; commonly assigned), in the previous office action dated March 19, 2008. However, in view of Applicants' claim amends and upon further consideration, the previous provisional rejection is hereby withdrawn.

Claims 1-6 and 24-27 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 41, 44-47 and 49-56 of copending U.S. Patent Application No.: 10/523,191 (2006/0143725; commonly assigned). Applicants' cancellation of claim 24 renders its rejection moot. As Applicants have not provided an appropriate terminal disclaimer, the rejection set forth on pp. 6-8 of the previous office action dated March 19, 2008 is maintained for reasons of record.

Conclusion

Claims 1-6 and 25-27 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. The claims are drawn to the same invention claimed earlier in the application and would have been finally rejected on the grounds and art of record in the next Office Action if they had been entered earlier in the application. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR§1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fereydoun G. Sajjadi, Ph.D.
Examiner, Art Unit 1633

/Anne Marie S. Wehbe/
Primary Examiner, Art Unit 1633